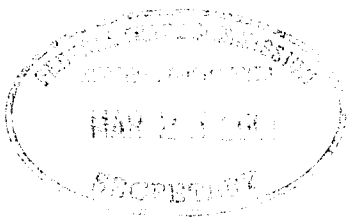
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



In the Matter of	)	
NATURAL ORGANICS, INC., a corporation, and	)	DOCKET NO. 9294
GERALD A. KESSLER, individually and as an officer of the corporation.	)	

TO: The Honorable James P. Timony
Administrative Law Judge

COMPLAINT COUNSEL'S STATUS REPORT AND STATEMENT OF THE CASE

Complaint counsel, in accordance with the Amended Scheduling Order issued on December 11, 2000, file this status report and statement of the case. Below, we report on compliance with discovery and the status of settlement negotiations, and we identify the legal and factual matters to be decided by Your Honor.

I. Introduction

This matter centers on the Commission's allegations that respondents made several unsubstantiated claims about Pedi-Active A.D.D., a dietary supplement, in violation of the FTC Act. The Commission's complaint in this matter alleges that the respondents deceptively claimed that Pedi-Active A.D.D. will (A) improve the attention span of children who have difficulty focusing on school work; (B) improve the scholastic performance of children who have difficulty focusing on school work; (C) improve the attention span of children who suffer from ADHD; (D) improve the scholastic performance of children who suffer from ADHD; and (E)

treat or mitigate ADHD or its symptoms.

According to the complaint, respondents targeted Pedi-Active A.D.D. to parents of children with Attention Deficit/Hyperactivity Disorder ("ADHD"). ADHD is a widely-recognized developmental disorder of childhood characterized by a persistent pattern of inattention and/or hyperactivity-impulsiveness that is more frequent and severe than is typically observed in individuals at a comparable level of development. ADHD was previously designated as Attention Deficit Disorder, or ADD. Accordingly, many people still refer to the disorder as "ADD." In common parlance, the terms ADHD and ADD are often used interchangeably.

The Commission issued its Complaint in this matter on August 9, 2000. On September 27, 2000, Your Honor issued a Scheduling Order calling for a hearing commencing on May 2, 2001. On October 12, 2000, however, respondents informed the Court that their lead counsel, Milton A. Bass, had been killed in an automobile accident. Respondents moved for a sixty-day stay in these proceedings to allow them to find new counsel and to allow such counsel to become familiar with the matter. Your Honor orally granted respondents' motion on October 18, 2000. Following the Notice of Appearance filed by respondents' new counsel on December 1, 2000, the parties proposed, and Your Honor granted, an amended Discovery Schedule that calls for a hearing that commences on June 19, 2001.

Respondents first marketed Pedi-Active A.D.D. in late 1996. Since early 1997, they have continuously advertised this product through a magazine advertisement (Complaint Exhibit A). Respondents have placed this ad at least fifty-four times during that period, and it is still in use. Respondents have also advertised Pedi-Active A.D.D. through a brochure that they have disseminated since early 1997 both directly to consumers and through health food stores that sell

the product (Complaint Exhibit B). Numerous third-party retailers have used copy from the advertisement and/or brochure in their own advertising of the product on the Internet.

In addition, from approximately March 1997 until approximately August 1998, respondents disseminated a letter (Complaint Exhibit C) to consumers who responded to the print advertisement. Respondents have also advertised Pedi-Active A.D.D. on Natural Organics' Web site (Complaint Exhibit D).

II. Discovery

The parties have conducted a considerable amount of discovery, and some significant amount remains. As discussed below, the parties have been unable to resolve how to complete discovery prior to April 13, 2001, which is the Scheduling Order's date for the close of discovery. As a result, complaint counsel respectfully request an immediate conference with Your Honor to discuss this issue.

A. Written Discovery

The parties exchanged Initial Disclosures on September 25, 2000. Complaint counsel provided supplemental responses on September 29, October 2, and December 28, 2000. Because it appeared to complaint counsel that respondents' initial disclosures were incomplete, we sent a subpoena duces tecum to respondents calling for them to provide responsive documents by November 2, 2000. The 60-day stay was granted during this period, and complaint counsel agreed with new counsel that the subpoena response could be provided in two waves – the first on January 12, 2001, and the second on February 7, 2001. Respondents responded in a timely manner, but withheld some responsive documents on the grounds that they were irrelevant and/or that their retrieval would be unduly burdensome. Complaint counsel moved to compel this

discovery, and Your Honor granted this motion, with certain limitations, on March 15, 2001.

Complaint counsel issued to respondents a second subpoena duces tecum on March 9, 2001. This subpoena, which calls for a limited volume of documents, has a return date of March 30, 2001.

Complaint counsel have also served on respondents two sets of interrogatories. Respondents received the first set on January 8, 2001 and responded in a timely manner on February 8, 2001. The second set was issued on March 9, 2001, and the return is pending.

Complaint counsel filed a Request for Admissions on October 4, 2000, shortly before the commencement of the sixty-day stay. Respondents responded in a timely manner on December 22, 2000.

Respondents filed their First Set of Interrogatories and a Request for Production of Documents on December 29, 2000. Complaint counsel responded in a timely manner on January 30, 2001.

The parties have exchanged initial fact and witness lists, as called for in the Scheduling Order. The parties are to exchange revised lists on March 23, 2001.

There is a significant amount of third-party discovery still outstanding. Most notably, complaint counsel issued subpoenas duces tecum to two independent laboratories and one laboratory affiliated with respondents. These subpoenas call for the production of documents relevant to these labs' testing of the chemical composition of Pedi-Active A.D.D. Respondents' counsel represents these three entities, and respondents and complaint counsel are in continuing discussions regarding the responses to these subpoenas. Although the time for moving to quash the subpoenas has passed, respondents have stated that they are working toward complying with

the subpoenas but are still unsure what burden, if any, is involved. Under these circumstances, complaint counsel have informed respondents that we will not oppose, on timeliness grounds, a motion to quash one or more of the subpoenas if the parties are unable to reach an agreement. At this time, complaint counsel are hopeful that the parties will not need the Court's intervention with regard to those subpoenas.

Complaint counsel also issued subpoenas duces tecum to several magazine publishers whose magazines published the Pedi-Active A.D.D. print advertisement (Complaint Exhibit A). These subpoenas simply call for the circulations of those magazines during the periods that the relevant advertisement ran. Those subpoenas have a return date of March 30, 2001.

Finally, complaint counsel issued a subpoena to the law firm of Ullman, Shapiro & Ullman, L.L.P.. We issued that subpoena because respondents have informed us that Robert Ullman, Milton Bass' former law partner, "will testify concerning Mr. Bass' well-established expertise in FTC and FDA matters. He will also testify regarding his knowledge as to how Mr. Bass interacted with clients such as Natural Organics." Complaint counsel assume that respondents will offer such testimony to support their defense of reliance on the advice of Mr. Bass, their main attorney during the period of time that they developed and first marketed Pedi-Active A.D.D.

B. Deposition Discovery

Presently, respondents have identified twelve potential non-expert witnesses.[1] Complaint counsel have completed six depositions of non-expert witnesses to date, and several more are

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[1] This number does not include any additions or deletions that may be reflected on the revised witness list that is due on March 23, 2001.

scheduled. Complaint counsel have not conducted the deposition of Gerald Kessler, the individual respondent, because of a dispute that arose shortly before Mr. Kessler was scheduled to be deposed on March 6, 2001. Complaint counsel issued a subpoena for Mr. Kessler's deposition on March 6, 2001, and respondents filed a motion to quash that subpoena on March 19, 2001. Complaint counsel filed our answer to that motion on March 22, 2001.

Complaint counsel also intend to conduct the depositions of appropriate representatives of the three testing laboratories from whom we have subpoenaed documents. We have informed respondents of this intention, and are awaiting a return of the subpoenaed documents before noticing these depositions.

Respondents also named six third-party fact witnesses to testify regarding respondents' good faith and other matters. In February, we proposed voluntary telephone depositions of these individuals, but respondents refused to schedule them until disputes over FDA discovery were settled. Having issued subpoenas, we have taken one deposition, have learned that one witness has decided not to testify, and we are attempting to schedule two more depositions. Neither complaint counsel nor respondents know the whereabouts of two others.

Respondents intend to take the deposition of David T. Read, an attorney with the Food and Drug Administration, who is complaint counsel's lone fact witness. Complaint counsel previously agreed to make Mr. Read available on February 21, 2001, but that deposition was postponed because respondents wanted to obtain certain documents subpoenaed from the FDA before taking his deposition. The FDA's motion to quash that subpoena is currently pending before Your Honor. Mr. Read continues to be available for a deposition.

C. Expert Discovery

Expert deposition scheduling has not run smoothly. As Your Honor knows, respondents designated fourteen expert witnesses on February 16, 2001. Although complaint counsel filed a Motion to Limit Expert Witnesses on February 26, 2001, we sent respondents a letter on February 27, 2001, requesting dates on which each of their designated experts would be available for deposition. We have argued to respondents that, given the number of busy schedules that must be coordinated for at least sixteen expert depositions, it was preferable to arrive at a tentative schedule as soon as possible, rather than attempting to do so later on truly short notice. Respondents refused to provide us with available dates for their experts, arguing that it was premature to provide such information. They cited as support the fact that Complaint Counsel's Motion to Limit Expert Witnesses was pending and that revised witness lists would be exchanged on March 23, 2001.

Your Honor denied, without prejudice, complaint counsel's Motion to Limit Expert Witnesses on the grounds that the motion was not ripe, as respondents' expert reports were due to be produced on March 14, 2001, and revised witness lists were to be exchanged on March 23, 2001. Respondents provided expert reports for all fourteen designated experts on March 14, 2001 and March 15, 2001. On March 20, 2001, respondents informed us that they are likely to include the names of all fourteen previously-designated experts (and perhaps one or more rebuttal experts) on the March 23, 2001 revised witness list.

As a result, complaint counsel anticipate refiling our Motion to Limit Expert Witnesses shortly. We have informed respondents of our intention and renewed our request that they provide us with dates on which their experts would be available. Rather than providing us with

dates, respondents have suggested that complaint counsel conduct three-hour telephone depositions of each of their experts. In addition, on March 22, 2001, respondents stated that they would not make some fact witnesses available for deposition until the situation with the experts was resolved.

There are now fifteen business days left before the April 13, 2001 close of discovery. There are sixteen expert depositions, and nine other depositions, remaining. The vast majority of the deponents are individuals that respondents have included on their witness lists. On March 20, 2001, we suggested to respondents that the parties file a joint motion requesting that the day for the close of discovery be pushed back several weeks to allow for those depositions to proceed appropriately. We emphasized, however, that we were unwilling to request that the trial date also be moved. On March 22, 2001, respondents informed us that they would agree to request an extension of the discovery schedule only if it also involved a similar delay in the beginning of the June hearing.

Under these circumstances, complaint counsel respectfully request that Your Honor schedule a conference for early during the week of March 26, 2001, to discuss only this scheduling issue. We recognize that the larger status conference originally scheduled for March 26, 2001, was postponed to accommodate the schedule of respondents' lead counsel, but we have come to an impasse on a vital issue and the close of discovery date is fast approaching. We believe that the discovery extension is needed no matter how Your Honor rules on our motion to limit the number of experts.

III. Status of Settlement Negotiations

On January 5, 2001, counsel for the parties met in our San Francisco offices to explore the possibilities for settlement. Mr. Kessler also was present at this meeting. In anticipation of the meeting, respondents submitted to complaint counsel a draft order that they stated they would be willing to sign. During that meeting, complaint counsel made two counteroffers. The following day, respondents informed complaint counsel that neither offer was acceptable, and settlement negotiations have not been revived.

IV. Factual and Legal Issues to be Decided

A. Jurisdiction

Jurisdiction is not contested.

B. Individual Liability

Complaint counsel will present substantial evidence that respondent Gerald A. Kessler formulates, directs, or controls the policies, acts, or practices of the corporation and is therefore liable for any deceptive representations contained in Natural Organics' advertisements (Complaint, ¶ 2). Mr. Kessler admits that he participated directly in virtually all of the acts or practices at issue. Specifically, he admits that he is the sole shareholder of Natural Organics (Respondents' Admission 52), has veto power over Natural Organics' advertising (Respondents' Admission 53), and participated in the development, preparation, or placement of Exhibits A, B, and D (Respondents' Admissions 54, 55 & 57). He also admits that he approved the content of those advertisements (Respondents' Admissions 58, 59 & 61) and controlled the activities of the employees of Natural Organics who participated in the development, preparation, or placement of all of the Exhibits to the Complaint (Respondents' Admissions 66, 67, & 69; Declaration of

John R. Fleder Opposing Complaint Counsel's Motion for Partial Summary Decision, at ¶ 19 ["Fleder Declaration"]). In light of those admissions, respondents have stated that "Mr. Kessler has clearly acknowledged his legal responsibilities for the acts of his company" (Fleder Declaration at ¶ 19).

Therefore, for the reasons stated above, complaint counsel do not anticipate that the Court will face any factual issues concerning Mr. Kessler's individual liability for any false or deceptive representations contained in the company's advertisements.

C. Advertising Dissemination

Respondents have admitted that they disseminated each of the advertisements that are attached to the Commission's complaint as Exhibits A-D (Respondents' Responses to Complaint Counsel's First Request for Admissions, 1, 12, 23 and 34). Complaint counsel will be introducing evidence regarding the extent of dissemination of these advertisements and, at this time, we do not anticipate that the court will need to decide any factual issues regarding such dissemination.

D. Ad Meaning

The complaint alleges that respondents' advertising has represented, expressly or by implication, that:

- Pedi-Active A.D.D. will treat or mitigate ADHD or its symptoms (Complaint ¶ 7E).
- Pedi-Active A.D.D. will improve the attention span of children who suffer from ADHD (Complaint ¶ 7C).
- Pedi-Active A.D.D. will improve the scholastic performance of children who

suffer from ADHD (Complaint ¶ 7D).

- Pedi-Active A.D.D. will improve the attention span of children who have difficulty focusing on school work (Complaint ¶ 7A).
- Pedi-Active A.D.D. will improve the scholastic performance of children who have difficulty focusing on school work (Complaint ¶ 7B).

Respondents deny that their advertising contains these representations (Answer ¶ 7).

Complaint Counsel contend that the Court can find that respondents made these claims based on its own review of the advertisements. While complaint counsel do not intend to offer a copy test into evidence, complaint counsel will present other extrinsic evidence that will assist the Court in evaluating the representations that respondents made in these advertisements. For example, we will introduce the evidence that phrases in the advertisements closely track the symptoms of ADHD and that clinicians who hear a description of child behavior with such terms would suspect ADHD. We will also introduce evidence that the terms "ADHD" and "ADD" are often used interchangeably.[2] Complaint counsel contend that the product's very name, Pedi-Active A.D.D., conveys a claim that this product will treat or mitigate ADHD or its symptoms.

Complaint counsel also will introduce evidence relating to respondents' intent when they created this product. In a press release issued shortly after the Commission filed the complaint in this matter, respondents stated that "Gerald Kessler, who founded Natural Organics 29 years ago, had the symptoms commonly referred to as Attention Deficit Disorder (A.D.D.) himself, as did his children and grandchildren. His difficulties and those of his family inspired the development

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[2] In this document, we refer to the disorder as "ADHD" because it is the technically correct term.

of Pedi-Active." Respondents clearly were targeting Pedi-Active A.D.D. to parents of children with ADHD.

Finally, complaint counsel will introduce evidence that consumers purchased this product because their children suffer from ADHD. Numerous parents who sent letters to respondents about their use of the product describe how their children have ADHD or how they are using the product as an alternative to Ritalin, a drug often prescribed for children with ADHD.

According to the expert reports that complaint counsel received, it appears that respondents intend to offer the testimony of Dr. Ivan Preston to refute these complaint allegations. To complaint counsel's knowledge, Dr. Preston has not conducted any consumer research relating to the claims respondents made in these advertisements.

In sum, the Court will need to determine whether Respondents did in fact made the claims that the complaint alleges.

E. Materiality of Respondents' Misrepresentations

The Court, as part of its deception analysis, will need to determine whether respondents' claims are material, i.e., "likely to affect a consumer's choice of or conduct regarding a product." Kraft, Inc., 114 F.T.C. 40, 133-34 (1991), aff'd, 970 F.2d 311 (7th Cir. 1992), cert. denied, 507 U.S. 909 (1993); Thompson Medical, 104 F.T.C. at 788, 816. The Commission presumes that challenged claims are material in any of the following circumstances: (1) The claims are express; (2) the claims are implied but evidence establishes that the advertiser intended to make the claims; (3) the claims significantly involve health; or (4) the claims pertain to the central characteristics of the product or service, such as claims regarding its purpose, safety, efficacy, or cost. Federal Trade Commission Policy Statement on Deception, appended to Cliffdale Assocs.,

Inc., 103 F.T.C. 174, 182-83 (1984); see Kraft, 114 F.T.C. at 133-134; Thompson Medical, 104 F.T.C. at 816-17. The claims and omissions that complaint counsel challenge in this matter are presumptively material: All involve health or relate directly to the purpose or efficacy of the product. Several, if not all, are implied claims that respondents intended to make.

F. Section 12 of the FTC Act

The complaint alleges that Pedi-Active A.D.D. is a "food" and/or "drug" within the meaning of Sections 12 and 15 of the FTC Act (Complaint ¶ 3). Respondents admit that Pedi-Active A.D.D. is a food (Respondents' Admission 71). Accordingly, if respondents' advertisements violate Section 5 of the FTC Act, those advertisements also violate Section 12 and 15. Therefore, complaint counsel does not anticipate that the Court will not need to decide any factual issues relating to Section 12.

G. Substantiation

The complaint alleges that respondents did not possess and rely upon a reasonable basis that substantiated the representations alleged in Paragraph 7 of the complaint (Complaint ¶ 9). Respondents deny that they lacked a reasonable basis to support these claims (Answer ¶ 9). If the Court finds that respondents made the claims that are alleged in the Commission's complaint, it will need to determine: (1) the level of substantiation necessary to substantiate those claims and (2) whether respondents possessed and relied upon that level of substantiation before making the claims.

1. Scientific Substantiation Standard

Complaint counsel will contend that each of respondents' claims must be substantiated with competent and reliable scientific evidence. In determining whether a particular

advertisement contains a claim of scientific proof, the Commission looks to whether the language and images in the ads at issue "imbue the ads with an aura of scientific support" which can be reasonably interpreted as implying a scientific level of support. Bristol-Myers Co., 102 F.T.C. 21, 329 (1983); Removatron 111 F.T.C. 206, 298 (1988), aff'd 884 F.2d 1489 (1st Cir. 1989). Complaint counsel will argue that respondents have strongly implied in all of their ads and promotional materials that the effectiveness of Pedi-Active A.D.D. is well-grounded in scientific support and research. As such, respondents "must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth." Removatron, 111 F.T.C. at 297.

If the Court finds that respondents have not implied a particular level of substantiation to reasonable consumers in particular advertisements, the Court must determine what level of substantiation constitutes a reasonable basis for the claims respondents made in those advertisements by weighing several factors set forth in Pfizer and subsequent cases. Thompson Medical Co., 104 F.T.C. 648, 813 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987); Bristol-Myers Co., 102 F.T.C. at 321; Pfizer, Inc., 81 F.T.C. 23 , 64 (1972). These factors include the type of claim, the nature of the product or service, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for claim, and the amount of substantiation experts in the relevant field believe is reasonable. Federal Trade Commission Policy Statement Regarding Advertising Substantiation, appended to Thompson Medical Co., Inc., 104 F.T.C. 839, 839-40 (1984) [hereinafter "Substantiation Statement"].

Complaint counsel contend that, based on Pfizer, respondents were required to possess competent and reliable scientific evidence supporting the claims alleged in the complaint. "In past cases involving health or safety issues, [the Commission has] required a relatively high level

of substantiation, typically scientific tests." Thompson Medical, 104 F.T.C. at 822 (footnote omitted); see also Simeon Management Corp., 87 F.T.C. 1184, 1230 (1976), aff'd, 579 F.2d 1137 (9th Cir. 1978).

Thus, the Court must evaluate whether respondents have implied in each of their Pedi-Active A.D.D. advertisements that the representations alleged in the complaint are supported by scientific evidence. If the Court concludes that respondents have not implied a particular level of substantiation in any particular Pedi-Active A.D.D. advertisements, the Court must analyze using the Pfizer factors whether respondents were required to possess scientific evidence as substantiation for the claims made in that advertisement.

2. Adequacy of Respondents' Substantiation

Complaint counsel contends that respondents did not possess competent and reliable scientific evidence at the time they disseminated the Pedi-Active A.D.D. advertisements. Complaint counsel intend to offer testimony from two experts, L. Eugene Arnold and Eric J. Murphy. Dr. Arnold will testify that he has analyzed the full body of substantiation materials offered by respondents and has conducted his own independent research of available scientific articles. Based on his analysis, he has concluded that respondents did not possess and rely upon adequate substantiation for their claims at the time they were made. Dr. Murphy has tested several specimens of Pedi-Active A.D.D. in his lipid laboratory and has determined that the product he tested contained amounts of certain ingredients that vary substantially from those which the respondents claim on their labeling and on a "certificate of analysis" they include in Pedi-Active A.D.D. bottles.

Respondents' substantiation materials include, inter alia, all of the materials considered

by the FDA with respect to the marketing by Riker Laboratories of an earlier product called "Deaner." This product included an ingredient ("DMAE") similar to the main ingredient in Pedi-Active A.D.D. The FDA in 1983 concluded that Deaner lacked substantial evidence of effectiveness. Although not relying upon the FDA proceedings as our principal expert evidence, we will offer a summary of the proceedings to explain FDA's role, its earlier approval of Deaner in the 1950s (purely on safety grounds), how the FDA proceeding provided notice to respondents regarding potential problems with the substantiation for their claims, and to affirm that FDA's actions are consistent with the views of our expert, Dr. Arnold.

According to the expert reports that respondents provided to complaint counsel, respondents appear to contend that the claims that the FTC has alleged have been made for Pedi-Active A.D.D. are substantiated by competent and reliable scientific evidence. Therefore, the issue before the court will be the adequacy of the studies and other documentation that Natural Organics possessed at the time the advertisements were disseminated.[3]

H. Defenses

Respondents' Answer raises four defenses. The first two are: (1) "Respondents' advertisements for the Product were and are truthful and not misleading;" and (2) "Respondents possessed at all relevant times a reasonable basis to substantiate the representations contained in their advertisements for the Product." These first two defenses appear to be merely rephrased denials of the complaint's allegations and do not, in and of themselves, raise distinct issues to be

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[3] One of respondents' designated experts, Eugene Lambert, apparently will testify regarding the Food and Drug Administration's regulation of dietary supplements. Complaint counsel question the relevance of such testimony to this proceeding. As a result, we are uncertain whether his testimony will require Your Honor to resolve any issue relevant to this proceeding.

decided by the Court.

Respondents also raise two additional defenses. They contend that the "product is lawfully sold as a dietary supplement and is not a drug." They also assert that "neither ADHD nor ADD are diseases or disease entities; there are no specific physical symptoms uniquely associated with ADD or ADHD; there is no physical test that can detect the supposed existence of ADHD or ADD; and none of the behaviors associated with ADHD or ADD are in themselves necessarily abnormal." These defenses appear to make the same point, which is that Pedi-Active A.D.D. is a food and not a drug.

Complaint counsel, however, contend that regardless of whether Pedi-Active A.D.D. is classified as a food or a drug, respondents are required to possess competent and reliable scientific evidence to substantiate their claims, as discussed above. This Court reached a similar conclusion in Schering Corp., 118 F.T.C. 1030 (1994). In that case, the Court found that Schering's advertisements claimed that Fibre Trim was an effective weight loss, weight control and appetite suppressant and made generalized claims about its health benefits. The Court found that, regardless of whether the product was a food or a drug, the company needed to possess competent and reliable scientific tests based upon its analysis of the advertisements under Pfizer. Id. at 1115.

In addition to the defenses raised in their Answer, respondents have indicated that they will assert a defense of reliance on advice of counsel. Complaint counsel contend that, because specific intent to deceive is not a necessary element of the violations here, reliance on advice of counsel is clearly irrelevant. See, e.g., FTC v. Algoma Lumber Co., 291 U.S. 67, 81 (1934); Kraft, 114 F.T.C. at 121.

I. Breadth of Order

If the Court determines that respondents violated the FTC Act, it will need to determine the breadth of a cease-and-desist order. Complaint counsel will contend that the Notice Order attached to the Complaint contains the appropriate relief to address respondents' violations of the FTC Act. To prevent respondents from engaging in these or similar acts or practices in the future, Part I of the Notice Order requires, in general, that respondents possess competent and reliable scientific evidence to substantiate the representations alleged in the complaint. Part II in general prohibits respondents from using the acronym "A.D.D." in the name Pedi-Active A.D.D. unless they possess competent and reliable scientific evidence that the product can treat or mitigate ADHD or its symptoms. Part III of the Notice Order contains fencing-in relief and prohibits the respondents from making any representation about the health benefits, performance, or efficacy of any food, drug or dietary supplement, unless they possess competent and reliable scientific evidence that substantiates the representation.

The Commission's ability to issue orders containing fencing-in requirements is well established. See, e.g., FTC v. Colgate-Palmolive Co., 380 U.S. 374, 394-95 (1965); Sears, Roebuck & Co. v. FTC, 676 F.2d 385, 391-92 (9th Cir. 1982); Kraft, 114 F.T.C. at 139. The Courts have recognized that the Commission has wide latitude to fashion orders that will prevent respondents from pursuing a course of conduct similar to that found to have been deceptive in the past. FTC v. National Lead Co., 352 U.S. 419, 429 (1957); Jacob Siegel Co. v. FTC, 327 U.S. 608, 612-13 (1946); Kraft, 114 F.T.C. at 139. The order, however, must be (1) "sufficiently clear and as precise as circumstances permit" and (2) "bear a reasonable relationship to the unlawful conduct found to exist." Kraft, 114 F.T.C. at 139. When evaluating whether a particular order

requirement bears a reasonable relationship to the unlawful conduct found to exist, the Commission considers several factors: (1) the deliberateness of the violation; (2) the seriousness of the violation, (3) the degree of transferability of the violation to other products, and (3) any history of prior violations. Id. All of these factors need not be present to justify broad fencing-in relief. See, e.g., Sears, Roebuck & Co., 676 F.2d at 392; Thompson Medical, 104 F.T.C. at 833.

Complaint counsel contend that the fencing relief proposed in the Notice Order is appropriate because the violations were deliberate. For example, complaint counsel will introduce evidence that respondents were aware that their advertisements for Pedi-Active A.D.D. may contain the representations alleged in the complaint, but failed to modify their advertisements. Respondents also did not rely on the advice of qualified scientists to determine the substantiation for their claims. Respondents should have known that reliance on the dubious qualifications of their Vice President of Research and Development probably would result in unsubstantiated claims about Pedi-Active A.D.D. Finally, respondents were aware of studies and other evidence which called into question the effectiveness of DMAE, an ingredient in Pedi-Active A.D.D., especially at the dosages the company originally recommended.

Complaint counsel also contend that the fencing relief proposed in the Notice Order is appropriate because the violations were serious. For example, complaint counsel will introduce evidence relating to the size and duration of the advertising campaign. Complaint counsel will also offer the testimony of Dr. Arnold who will testify that consumers cannot judge the truth or falsity of the claims. Moreover, these violations are serious because of the high cost of the product and because the claims that we are challenging are the central claims of the campaign.

Complaint counsel also contend that respondents' practices regarding the advertising of

Pedi-Active A.D.D. could be easily transferred to the marketing of other food, drug or dietary supplement. In particular, respondents' failure to rely on the advice of qualified scientists when evaluating their substantiation tends to show that a broader order overseeing respondent's practices is warranted. In addition, respondents could, with no difficulty, make the same unsubstantiated efficacy claims in advertisements for other children's products or products that contain any of the same ingredients as Pedi-Active A.D.D.

Respondents have stated that they plan to present evidence regarding (1) "Respondents' good faith actions regarding the supply of raw materials, including the ingredients in Pedi-Active A.D.D., to the dietary supplement industry generally, and to Respondents;" (2) "Respondents' good faith conduct and fair dealing in business;" (3) "Respondents' commitment to quality, integrity and good faith business practices;" and (4) "Respondents' good faith effort to comply with the Federal Trade Commission Act and all other applicable laws and regulations." Letter from John Fleder to Matthew Gold (Jan. 19, 2001) (identifying non-expert witnesses). While complaint counsel questions the relevance of some of these facts to the present proceeding, at the present time, complaint counsel is continuing to conduct discovery on these issues. In particular, complaint counsel is evaluating respondents' statements in print advertisements and other marketing materials that independent laboratories confirm their product formulations. We have reason to suspect that respondents, contrary to these statements, do not possess independent laboratory tests confirming the chemical composition of many of their products.

According to the expert reports that complaint counsel received, it appears that respondents intend to offer post-claim substantiation evidence. For example, some, if not all, of the substantiation experts that they named have relied, in part, upon materials that respondents

have never provided as support for their claims. While the Court may consider such post-claim evidence when determining the breath of the order to be entered against a firm, such evidence is not relevant regarding liability. Substantiation Statement, 104 F.T.C. at 840-41. Complaint counsel will introduce the testimony of Dr. Arnold that the claims alleged in the complaint would still be unsubstantiated if made today.

Therefore, if the Court finds that respondents are liable as alleged in the complaint, the Court will need to determine whether a multi-order, multi-claim order is appropriate based upon the seriousness and deliberateness of the violation, and degree of transferability of the practice. In addition, the Court may need to consider post-claim substantiation evidence that the respondents introduces when it evaluates the appropriateness of the order relief.

Respectfully submitted,

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Dated: March 23, 2001

CERTIFICATE OF SERVICE

This certifies that a copy of Complaint Counsel's Status Report and Statement of the Case was served by facsimile on March 23, 2001, on the following:

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